

**REMARKS**

Claims 89-117 are pending. Claims 89-110 and 114 are under examination.

The rejection of claims 89-110 and 114 under 35 U.S.C. § 103(a) as allegedly obvious over Froesch et al., Proceeding of the American Association for Cancer Research, Annual Meeting, 89:13 (March 1998), in view of Takayama et al., Cancer Res. 58:3116-3131 (1998), Noordzij et al., J. Urology, 158:1880-1885 (1997), and Sano et al., U.S. Patent No. 5,665,539, is respectfully traversed. Applicant respectfully maintains, for the reasons of record, that the claimed methods are unobvious over Froesch et al., alone or in combination with Takayama et al., Noordzij et al., and/or Sano et al.

Applicant respectfully maintains, for the reasons of record, that Froesch et al. does not teach or suggest the claimed methods for determining the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. At best and as discussed previously on the record, Froesch et al. describes the observation that BAG-1L is expressed in prostate cancers and enhances androgen receptor function. However, Froesch et al. provides no teaching or suggestion that the level of BAG-1 gene expression can be used to determine the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. In fact, Froesch et al. provides no teaching or suggestion of any relative expression level of BAG-1, let alone overexpression, only that BAG-1 was detected in the prostate cancer lines and archival prostate tumor specimens tested. The specification teaches that BAG-1 is expressed in normal prostate, albeit in a smaller percentage of cells (41% in normal versus 78% in cancer cells)(see specification page 41, lines 7-12). Thus, it is the subject specification, not Froesch et al., that teaches overexpression, that is, higher intensity BAG-1 immunostaining, was found to be, for example, associated with a higher incidence of metastatic relapse (page 41, lines 4-7). Froesch et al. provides no teaching or suggestion of the level of BAG-1 expression, let alone overexpression, merely that BAG-1 is expressed in prostate cancer cell lines and tissue samples.

With respect to Takayama et al., Applicant respectfully maintains the position of record. Nevertheless, Applicant notes for the record that the present application is a U.S. national stage

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application of PCT US00/18758 having an international filing date of July 7, 2000, which claims the benefit of priority of U.S. application serial No. 09/350,518, filed July 9, 1999. The date of publication of Takayama et al. is July 15, 1998. Accordingly, Takayama et al. was published less than one year prior to the priority date of the present application. As such, Takayama et al., at best, would be considered prior art under § 102(a). Submitted herewith is a Rule 132 Declaration executed by the inventor, Dr. John C. Reed, attesting that he is the sole inventor and that the co-authors of the Takayama et al. reference worked under his direction and supervision. Therefore, Applicant respectfully submits that the Takayama et al. reference is not applicable as prior art. Accordingly, Applicant respectfully requests that the obviousness rejection as it relates to Takayama et al. be withdrawn.

Upon the removal of Takayama et al. as discussed above, any obviousness rejection would need to be viewed, at best, as a combination of Froesch et al. in view of Noordzij et al. and/or Sano et al. However, Applicant further maintains, for the reasons of record, that neither of Noordzij et al. and/or Sano et al. can be considered to cure the deficiencies of Froesch et al. As discussed previously on the record, Noordzij et al. found no correlation with Bcl-2. “The bcl-2 scores did not correlate with tumor stage or grade” (abstract; emphasis added). Noordzij et al. further indicated that “[A]ndrogen receptor scores were marginally related to tumor grade, but not to tumor stage” (abstract). Noordzij et al. stated that a “prognostic value of bcl-2 or androgen receptor in pretreatment transurethral resection specimens was not found” (see abstract and page 1883, right column, first complete paragraph). Noordzij et al. found only a combined bcl-2/androgen receptor score to be an independent prognostic marker to predict clinical progression (see abstract and page 1883, right column, third paragraph). Given the lack of prognostic value of bcl-2 as specifically stated in Noordzij et al., one skilled in the art would have had no reasonable expectation of success that determining BAG-1 gene expression level in cancerous prostate tissue would allow determining the risk of tumor recurrence or spread in a prostate cancer patient. Furthermore, Sano et al., at best, describes an immuno-PCT method. Therefore, Applicant maintains that Noordzij et al. and/or Sano et al. cannot cure the deficiencies of Froesch et al.

Applicant respectfully maintains that Takayama et al. cannot be considered proper prior art and that Froesch et al., alone or in combination with Noordzij et al. and/or Sano et al., does

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not teach or suggest the claimed methods. Absent such a teaching or suggestion, Applicant respectfully submits that the claimed methods are unobvious over Froesch et al., alone or in combination with Noordzij et al. and/or Sano et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In light of the remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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